IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA ex rel.
COREY SCOTT **PLAINTIFF**

v. **CIVIL ACTION NO.** _____

HEMISPHERX BIOPHARMA, INC.
and ENGITECH, LLC **DEFENDANTS**

CV-04-HGD-2788-S

Filed Under Seal

COMPLAINT
(Jury Trial Requested)

I.

PARTIES

1. Corey Scott is a U.S. citizen and a resident of the State of Alabama and a former employee of Defendant, Engitech, LLC ("Engitech"). Corey Scott is the original source of the facts and information hereinafter set forth concerning the activities of the defendants. The facts averred herein are based entirely upon his personal observation and documents in his possession.

2. Hemispherx Biopharma, Inc. ("HBI") is a corporation with its principal place of business in Philadelphia, Pennsylvania. HBI is principally engaged in the manufacture and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulations of the U.S. Food and Drug Administration.

3. Engitech is a corporation with its principal place of business located in Marietta, Georgia. Engitech is principally engaged in the sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the U.S. Food and Drug

Administration.

II.

JURISDICTION

4. At all times material hereto, Defendants regularly conducted substantial business within the State of Alabama, maintained permanent employees and offices, and made and are making significant sales within Alabama, and are thus subject to personal jurisdiction in the State of Alabama. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 31 U.S.C. § 3730(b) and 3732(a).

5. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and © and 31 U.S.C. §3732(a).

III.

FACTS

6. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is the original source.

7. In 1989, Interferon Sciences, Inc. ("ISI") obtained approval from the U.S. Food and Drug Administration (hereinafter the "FDA") to market Interferon Alfa-N3 (Human Leukocyte derived) for the intralesional treatment of refractory or recurring external condyloma acuminatum ("genital warts"), in dosages of 5 MIU/vial in patients 18 years of age or older. The FDA has never approved the use of this product for any other purpose or in any other dosage.

8. ISI began marketing the product under the trade name "Alferon N." ISI conducted clinical trials related to use of Alferon N for treatment of HIV and Hepatitis C. If approved for these uses, the revenue potential of Alferon N could increase exponentially. Not only would such approval expand the types of treatable patients, the treatment of those conditions would require significantly

higher dosages than that which had been approved by the FDA. In response to ISI's test results, however, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of the drug for these purposes.

9. On March 11, 2003, HBI entered into two agreements with ISI. As a result of the first agreement, HBI acquired ISI's inventory of Alferon N and a limited license for the production, manufacturing, use, marketing and sale of the product.

10. Pursuant to the second agreement, HBI purchased all intellectual property rights, including patent rights to Alferon N.

11. After obtaining the license to market and sell Alferon N, HBI formed a scheme to increase the sales of Alferon N while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of the drug. The scheme consisted of an elaborate and clandestine promotion of off-label uses of Alferon N, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency, and in particular for the off-label treatment of Cancer, Multiple Sclerosis, HIV, and Hepatitis C.

12. This scheme was carried out in concert with defendant Engitech for the nationwide distribution of Alferon N. The scheme involved, among other things:

a. the formation of a nationwide network of employees falsely referred to as "Therapeutic Sales Representatives" whose actual assigned duties consisted entirely of conventional direct sales activities and which did not include any legitimate scientific activity;

b. the illegal direct solicitation of physicians for off-label uses;

c. the making of false statements to physicians concerning the efficacy and safety of Alferon N for off-label uses;

d. upon information and belief, the making of such false statements directly to

the Veterans Administration concerning the safety and efficacy of Alferon N for off-label uses;

e. the charging of full price for drugs actually being used in experimental trials and thus subject to federal price restriction;

f. the systematic avoidance of filing requirements with the FDA;

g. the deliberate avoidance of the FDA's classification of Alferon N as to its therapeutic equivalency and thus the avoidance of medicare and medicaid price limitations based on therapeutic equivalency;

h. the use of active concealment to avoid the FDA's enforcement mechanisms and the resultant mandatory interruption of medicare and medicaid payments for Alferon N prescriptions;

I. The use of active concealment to avoid the "formulary" policies of various state agencies administering medicare and medicaid programs and which are intended to refuse payment for uses of drugs which are not medically recognized as statutorily defined;

j. the active training of Engitech employees to market and sell Alferon N for off-label use and medicaid reimbursement; and

k. use of misleading and deceptive statements in public securities filings, including intentional misrepresentations and material omissions concerning the true nature of the defendants' marketing scheme.

13. Publicly, HBI acknowledges that the FDA has only approved Alferon N for a limited purpose, and that "[u]se of Alferon N for other [non-approved] indications will require regulation approval."

14. Therefore, according to its public filings, HBI's "marketing and sales plan" for Alferon N "consists of engaging the services of sales contract organizations and supplementing their

sales efforts with marketing support. This marketing support consists of building awareness of Alferon N with physicians as a successful and effective treatment **of refractory or recurring genital warts** in patients of age 18 or older and to assist primary prescribers in expanding their practice."

15. Notwithstanding these representations, the Defendants have devised an elaborate and determined plan to sell Alferon N for unapproved uses. Indeed, not only is off-label marketing a component of the Defendants' sales plan, it is the primary objective.

16. The approved use of Alferon N – treatment for genital warts – is for a very limited purpose and dosage. The Defendants stand to generate the vast majority of revenue from off label sales for the treatment of cancer, HIV, MS, and Hepatitis-C, which would require use of the drug with substantially more frequency and dosage than that which is associated with the approved treatment for genital warts. Accordingly, the Defendants' sales force is instructed that their primary objective is to sell Alferon N to treat "chronic use for MS, Hep C and Oncology."

17. Publicly, HBI admits that efficacy testing for off label uses is either non-existent or incomplete.

18. In actuality, however, HBI's sales representatives are instructed to represent to oncologists and neurologists that Alferon N has undergone efficacy testing for unapproved uses.

19. The sales personnel are instructed to represent to oncologists and neurologists that efficacy testing demonstrates that:

(a) Alferon has "clinical advantages in side effect profile and pharmacology" over other drugs used to treat cancer and MS;

(b) Alferon enjoys "a clinical advantage over other interferons" in side effects;

© Alferon is "accepted by oncologists as safe and effective" for the treatment of cancer;

(d) Alferon is "recognized as a viable cancer treatment option"

(e) "neurologists use it to treat MS"

(f) "its effectiveness has been studied"

(g) Alferon N is "10-100 times more biologically active than [FDA approved drugs] which treat cancer, MS, HIV and Hepatitis C."

20. To support these statements, the sales reps are provided with summary information concerning preliminary efficacy testing of Alferon on patients suffering from multiple sclerosis and brain lesions at dosages that significantly exceeded that which was approved by the FDA.

21. These materials disclosed adverse events which resulted from the testing, but the sales reps were told not to discuss the materials with the physicians.

22. The tests related to "poster presentations," which do not undergo the rigors of evaluation associated with peer reviewed journals.

23. In actuality, the conclusion of the studies is that "further studies were needed" and "warranted" to determine the efficacy of Alferon for MS patients.

24. Nevertheless, the sales force was told to represent to oncologists and neurologists that the results of the study were "compelling and positive for the efficaciousness and tolerability of Alferon."

25. In support of the identified "goal" to "meet the needs of oncology and neurology specialities," the Defendants' marketing materials provided a step-by-step tutorial on how to convince an oncologist or neurologist to prescribe Alferon as "interferon therapy" and for other uses associated with the treatment of cancer, multiple sclerosis, HIV and Hepatitis C.

26. The Defendants' marketing program is specifically targeted to overcome objections of conscientious physicians. Indeed, an entire "workshop" was devoted to overcoming a doctor's refusal to use the drug because it was not indicated for the proposed use.

27. Entitled "Objection Handling," the workshop materials teach representatives how to respond to doctors who say "I won't use your drug because it is not indicated." The sales representatives are instructed that these physicians are usually not telling the truth, but are most likely saying this because the Defendants "have not provided the physician [with] a good reason to WANT TO PRESCRIBE Alferon." The materials then explain how the sales representative is to convince the oncologist or neurologist to prescribe Alferon for their cancer and MS patients.

28. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

29. There is no valid scientific evidence to support the contention that Alferon N is safe and effective for the treatment of Cancer, Multiple Sclerosis, HIV or Hepatitis C. There is no valid scientific evidence concerning the therapeutic equivalence of Alferon N in any of these diseases.

30. Off-label uses of Alferon N which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, are beyond the scope of uses designed by federal law and regulations, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the medicare and medicaid programs.

31. Although the sales agents are employees of Engitech, Inc., they are agents of HBI, and HBI is responsible for their conduct and for the improper sales of Alferon N for off label uses. Indeed, HBI admits in public filings that they "outsource certain components of our . . . marketing

and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group."

32. Since the implementation of the Defendants' off-label marketing scheme, sales of Alferon N have increased significantly. Sales of Alferon N are projected to exceed $21.5 million annually by the end of 2005. Upon information and belief, more than 50% of Alferon sales are accounted for by off-label use.

33. HBI's off label marketing practices of Alferon N are only the latest in a series of similar FDA violations.

34. On or about October 15, 1998, the Division of Drug Marketing, Advertising, and Communications (DDMAC) notified William Carter, CEO of HBI that HBI was in violation of the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, for promotion of "Ampligen" as safe and effective for treatment of persons with Human Immune Deficiency Virus (HIV) prior to FDA approval.

35. On or about October 29, 1998, HBI assured the DDMAC that it would discontinue the unlawful marketing of Ampligen.

36. Despite HBI's assurance, the DDMAC determined that HBI continued to market and sell Ampligen for unapproved uses. On or about July 7, 2000, the DDMAC notified HBI of its determination that its marketing materials were not only illegal, but deceptive and misleading, as they did not disclose the serious side effects experienced by HIV patients who had been treated with Ampligen.

37. Engitech's sales force has been told that "Ampligen is in the pipeline." Upon information and belief, HBI continues to market and sell Ampligen for unapproved uses, and receives revenue generated through the submission of false claims.

COUNT I

DELIBERATE AVOIDANCE OF FDA REGULATIONS/MEDICARE AND MEDICAID FINANCED SALES

38. Plaintiff incorporates all preceding numbered paragraphs 1-37.

39. A significant percentage of patients who use or have used Alferon N for off-label purposes are persons whose prescriptions are paid for in whole or in part by state administered medical assistance programs which receive 90% reimbursement from the federal government, to wit, medicare and medicaid.

40. The medicare and medicaid programs of the federal government include detailed provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full federal participation ("FFP"), price controls on prescription drugs, and drug manufacturer rebate agreements. These laws and regulations include, inter alia, as set forth as 42 U.S.C. § 1395y (c), that no federal payment shall be made in the case of a prescription drug for which the FDA has issued a notice of hearing regarding the effectiveness of the drug. Thus, the taking of a regulatory action by the FDA against the sale and promotion of a drug will, in circumstances, immediately interrupt the flow of federal funds for reimbursements of prescriptions written for the drug.

41. Direct promotion of off-label usage of a drug constitutes "labeling" as defined by the food and drug laws of the United States. It is reasonably certain, and Defendants are aware, that if the FDA became aware of its extensive program of illegal promotion of off-label uses of Alferon N, the FDA would take administrative action against Defendants, including, among other things, a notice of hearing regarding the effectiveness of Alferon N for the promoted off-label uses. Such a notice would, by federal statute, instantly interrupt the flow of federal funds for reimbursement for

off-label prescriptions.

42. Defendants have, as alleged, actively concealed its off-label promotion of Alferon N from the FDA. Said active concealment is motivated by the desire to, and has had the effect of, preserving the flow of federal funds to reimburse Alferon N prescriptions. Said active concealment constitutes a pattern of fraudulent conduct through which federal payments are derived, and constitutes False Claims within the meaning of 31 U.S.C. § 3729.

COUNT II

AVOIDING FEDERAL PRICE CONTROLS/EXPERIMENTAL USE OF DRUG

43. Plaintiff incorporates all preceding numbered paragraphs 1-42.

44. Federal law, in particular 21 C.F.R. § 312.7, imposes price controls on investigational new drugs used in clinical trials. The regulations state that charging for an investigational new drug is not permitted without FDA approval.

45. Defendants have launched a nationwide illegal program of experimentation with Alferon N. Although Defendants have actually commenced certain legitimate clinical trials of Alferon N to control pain in limited circumstances, Defendants have simultaneously encouraged and caused many physicians to experiment with Alferon N for off-label uses. These experimental programs are informal, generally unscientific, and not reported to the FDA. These informal experiments have been conducted for the dual purpose of increasing sales of Alferon N while at the same time developing data for possible use with the FDA. These informal experiments were conducted by means of prescriptions to patients whose prescriptions have been paid for, in a substantial number of cases, by medicare and medicaid at regular prices.

46. Defendant's deliberate avoidance of federal price controls on the experimental investigational use of drugs has caused financial harm to the federal government by inducing the

federal government to pay for drug prescriptions for which payment is prohibited by federal law. Defendant's deliberate avoidance of federal price controls on experimental use of drugs constitutes a pattern of fraudulent conduct which induced payments by the federal government, and constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT III

VIOLATING STATE FORMULARIES/MEDICARE AND MEDICAID

47. Plaintiff incorporates all preceding numbered paragraphs 1-46.

48. Under the statutes and regulations establishing the medicare and medicaid programs, the individual states are permitted to establish drug utilization review boards and formularies which define those prescription drugs and their uses for which a state agency will make reimbursement under their medicare programs. Federal law, in particular 42 U.S.C. § 1396r-8, requires a state formulary to include medically accepted uses of prescription drugs by reference to the publications set forth, in ¶ 11, supra.

49. Many state medicare agencies intend not to reimburse for prescription drugs for uses not set forth in the publications referred to in ¶ 11, supra, in that the states do not intend to spend money on prescriptions not recognized as medically necessary in sources specified by federal law. However, many states lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted according to the federally specified publications. This lack of technical ability represents a loop-hole in the scheme of the medicare and medicaid programs.

50. Defendants have recognized and aggressively exploited this loop-hole by means of a direct, illegal, nationwide program of promotion of off-label use of Alferon N by physicians.

Defendants have conducted this program of promotion knowing that prescriptions for Alferon N are generally reimbursed by the state medicare programs even though individual prescriptions for Alferon N fall outside of state formularies because they are not medically accepted.

51. Defendants' aggressive, illegal scheme of off-label promotion has induced federal payments through a pattern of fraudulent conduct by causing the states, and thus the federal government, to pay out sums to claimants they did not intend, to benefit. Defendants' conduct constitutes False Claims within the meaning of 31 U.S.C. § 3729.

COUNT IV

FALSE STATEMENTS TO PHYSICIANS

52. Plaintiff incorporates all preceding numbered paragraphs 1-51.

53. As part of its illegal off-market promotion of Alferon N, Defendants have instructed and caused its sales personnel and its medical liaison employees to make false statements to physicians, and to provide physicians with written materials containing false statements, concerning the safety and efficacy of Alferon N for off-label uses. These statements were made with the intent of, and had the effect of, inducing physicians to increase their off-label prescription of Alferon N. This increased off-label prescription of Alferon N caused harm to the federal government by increasing the number of medicare claims for Alferon N prescriptions.

54. The false statements made by Defendants employees to physicians have included representations that scientific evidence exists that Alferon N is an effective treatment for Cancer, Multiple Sclerosis, HIV and Hepatitis C. The false statements also include representations that Alferon N is known to be safe and effective in dosages of up in excess of 5 MIU/vial in all populations. The false statements include representations that clinical trials are ongoing or planned with respect to each of the above off-label uses. Each of these statements is unsupported by any

legitimate scientific evidence.

55. Defendants' false statements made to physicians were a pattern of fraud designed to induce payments by the federal government, and constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT V

AVOIDING PRICE CONTROLS BASED ON THERAPEUTIC EQUIVALENCY

56. Plaintiff incorporates all preceding numbered paragraphs 1-55.

57. The federal laws establishing the medicare and medicaid programs contain drug price controls based on therapeutic equivalencies, as established by the FDA in an official publication (42 U.S.C. § 1396r-8). Defendants' illegal program of off-label promotion and avoidance of proper FDA procedures for approval of a new drug use has resulted in the lack of any classification of Alferon N for therapeutic equivalency as to its off-label uses, such as treatment for Cancer, Multiple Sclerosis, HIV and Hepatitis C. As a result, Alferon N has not been subject to federal medicare price limits based on therapeutic equivalency.

58. The federal government has been harmed by this avoidance of a rating of Alferon N for therapeutic equivalency because other less expensive drugs are capable of conferring the same benefit as Alferon N for various off-label uses. If Alferon N were properly rated for therapeutic equivalency for the "off-label" uses, the states and the federal government would be able to achieve the same benefits for less money.

59. Defendant's illegal scheme of off-label promotion is a deliberate avoidance of federal price controls based on therapeutic equivalency, and constitutes inducement of federal payments through a pattern of fraudulent conduct and constitutes a False Claim within the meaning of 31. U.S.C. § 3729.

COUNT VI

FRUSTRATION OF FEDERAL POLICY

60. Plaintiff incorporates all preceding numbered paragraphs 1-59.

61. All of the conduct referred to above, to wit, off-label promotion of Alferon N in violation of FDA rules, deliberate avoidance of federal price controls of experimental drugs and drugs with therapeutic equivalents, inducement of physicians and the Veterans Administration to prescribe or purchase Alferon N by use of false statements, and avoidance of state formulary restrictions, are substantial and deliberate frustrations of clear federal law, regulation, and policy concerning the promotion and sale of prescription drugs.

62. Defendants have sold millions of dollars worth of Alferon N knowing that such sales were directly or indirectly paid for by the federal government, and knowing that such sales and the promotions leading to them represented a direct frustration and violation of federal law, regulation and policy, and knowing that the federal government was paying out sums on behalf of beneficiaries it did not intend to benefit, to wit, veterans and medicare and medicaid patients who were prescribed experimental or off-label uses of Alferon N as a result of Defendant's illegal promotions and schemes. Defendants' overall pattern of conduct aimed at avoiding federal law while inducing the payment of federal funds was a pattern of fraud to induce federal payments and constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT VII

DIRECT SALES TO VETERANS ADMINISTRATION

63. Plaintiff incorporates all preceding numbered paragraphs 1-62.

64. Upon information and belief, the Defendants have sold, and is selling, significant

quantities of drugs to the Veterans Administration for off-label uses.

65. The Defendants are conducting and have conducted, illegal direct promotion of off-label uses of drugs directly to the Veterans Administration, and to Veterans Administration physicians and pharmacists. These illegal promotional activities have resulted in greatly increased use of drugs by the Veterans Administration. Defendants' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United States and the deliberate active concealment of those violations. Defendants' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729.

COUNT VIII

CONSPIRACY

66. Plaintiff incorporates all preceding numbered paragraphs 1-65.

67. As described above, the Defendants entered into an agreement, combination and conspiracy to market drugs for off label uses and Medicaid reimbursement. This constitutes a conspiracy to defraud the government, pursuant to 18 U.S.C. § 286.

COUNT IX

ILLEGAL PROMOTION OF AMPLIGEN

68. Plaintiff incorporates all preceding numbered paragraphs 1-67.

69. Upon information and belief, HBI and / or the Defendants in concert, have used the same illegal means and methods of promoting the off-label use of Ampligen which they have used, as alleged above, to promote Alferon N. A substantial portion of all Ampligen prescriptions are paid for, indirectly, by the federal government under the medicare and medicaid programs. The use of

illegal and prohibited methods of promoting Ampligen has caused direct financial harm to the federal government by substantially increasing the amount of money spent on reimbursements of Ampligen prescriptions. Such illegal promotion constitutes a pattern of fraudulent activity to induce claims against the federal government, and is a False Claim within the meaning of 31 U.S.C. § 3729.

WHEREFORE, the plaintiff demands judgment on behalf of the United States, together with all costs, fees, awards, and interest allowed by 31 U.S.C. § 3730.

Respectfully Submitted, this the 20th day of September, 2004.

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